K061622
Page 1 of 2

510(k) Summary of Safety and Effectiveness

Submitter

Photonic Optische Geräte GesmbH & CoKG
Seeböckgasse 59
A-1160 Vienna, Austria
Mr. Dieter Feger (GM)
phone: +43(1)4865691-0
prepared: 13th March 2006

MAR 05 2007

Device Submitted

Xenon/Metal halide light source with fiber

Proprietary Name

PS series

Common Name

Light source

Predicate Devices

Applicant	Predicate Device	510(k)	class, code, 21CFR
Cogent/WelchAllyn	Solartec Source ST270 (CL300)	K983714	II, FFS, 876.1500
Cogent/WelchAllyn	Micro Link endoscopic fiber cable	K001698	II, FFS&KOD 876.1500 II, HBI&FST, 878.4580
Isolux America	1300 XSBP	K022384	II, HET, 884.1720
Isolux America	1125 XSB	K052979	II, HBI, 878.4580 I, EAZ, 872.4630
Isolux America	Fiber optic surgical headlight	K991572	II, FST, 878.4580
Isolux America	fiberoptic cable	K991208	II, HBI, 878.4580

Device Description

The cold light sources of the PS series consist of short arc metal-halide or xenon lamps, driven by electronic ballasts. Optical components such as mirrors, lenses, filters and coatings focus the light to a small diameter of typically 1.5-4mm. Fiber light guides (single or bundles) transmit the light to the application such as endoscopes.

Intended Use

The device is used to provide light for endoscopic devices. Those devices can be connected directly to the light source or by fiber bundles or single fibers. The device is intended for prescription use only.

Technological Characteristics Similarities

The light sources PS series with fibers are similar in use, design and function to those from Isolux and Cogent (WelchAllyn).

Performance Data

No performance data is required for this Class II device nor requested by FDA (ODE).

Safety

The device is designed for and fully meets following international safety standards:

- IEC 60601-1:1988 +A1:1991 +A2:1995
- IEC 60601-1-2:2001
- IEC 60601-2-18:1996 +A1:2000
- UL2601-1:1997
- CAN/CSA-C22.2 No. 601-1-M90
- 47 CFR Ch.1 Part 15 (FCC)
- IEC 60601-2-41:2000 (in accordance to UV measurements)

Effectiveness

Metal halide or xenon arc lamps produce white light similar to sunlight. All light transmitting elements such as mirrors, lenses, filters and coatings are determined not to change the color temperature of the system.

This device uses an extra short arc lamp, which improves the effectiveness of focusing the light with the help of optics into a small fiber (single or bundle) with diameters typically between 1.5-4mm as the predicate device.

Conclusion

The technological differences to the predicate devices do not affect the safety or efficacy of the submitted devices, therefore leads to the conclusion, that the cold light series PS including fibers are substantial equivalent to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Photonic Optische Geräte GesmbH & CoKG
c/o Mr. Stefan Preiss
TPR Program Manager
TÜV Product Service, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

MAR 0 5 2007

Re: K061622
Trade/Device Name: PS series with fiber light guide
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FFS, GCT and FCW
Dated: January 23, 2007
Received: January 29, 2007

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K061622**

Device Name: PS series with fiber light guide

Indications For Use:

The device is used to provide light for endoscopic devices. Those devices can be connected directly to the light source or by fiber bundles or single fibers. The device is intended for prescription use only.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: **NO** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061622